INFORMATIONAL LETTER NO.1500

TO: Iowa Medicaid Physicians, Dentists, Advanced Registered Nurse Practitioners, Therapeutically Certified Optometrists, Podiatrists, Pharmacies, Home Health Agencies, Rural Health Clinics, Clinics, Skilled Nursing Facilities, Intermediate Care Facilities, Community Mental Health, Family Planning, Residential Care Facilities, ICF/ID State and Community Based ICF/ID Providers

FROM: Iowa Department of Human Services, Iowa Medicaid Enterprise

DATE: April 21, 2015

RE: Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: June 1, 2015

1. **Changes to the Preferred Drug List (PDL) Effective June 1, 2015.** Refer to complete PDL located at [www.iowamedicaidpdl.com](http://www.iowamedicaidpdl.com).

<table>
<thead>
<tr>
<th>Preferred</th>
<th>Non-Preferred</th>
<th>Recommended</th>
<th>Non-Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acamprosate</td>
<td>Afrezza</td>
<td>Revlimid</td>
<td>Lynparza</td>
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<tr>
<td>Clomipramine†</td>
<td>Akynzeo†</td>
<td></td>
<td>Obizur</td>
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<tr>
<td>Colchicine†</td>
<td>Amlodipine/Valsartan†</td>
<td></td>
<td>Tybost</td>
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<tr>
<td>Diamox</td>
<td>Amlodipine/Valsartan/HCTZ†</td>
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<tr>
<td>Duloxetine</td>
<td>Anafranil</td>
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<tr>
<td>Entacapone</td>
<td>Antabuse</td>
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<td>Eszopiclone</td>
<td>Arnuity Ellipta</td>
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<tr>
<td>Harvoni†</td>
<td>Belsomra†</td>
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<tr>
<td>HyQvia</td>
<td>Bunavail†</td>
<td></td>
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<tr>
<td>Ivermectin Tablets</td>
<td>Ceftibuten</td>
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<tr>
<td>Ritalin LA†</td>
<td>Celecoxib†</td>
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<tr>
<td>Rivastigmine‡</td>
<td>Chlorpromazine‡</td>
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<tr>
<td>Tanzeum†</td>
<td>Comtan</td>
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<tr>
<td>Valsartan†</td>
<td>Diovan†</td>
<td></td>
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<td>Viekira Pak†</td>
<td>Donepezil 23mg Tablets‡</td>
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<td>Zaleplon</td>
<td>Doral</td>
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<td>Esbriet</td>
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<td>Exelon</td>
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<tr>
<td></td>
<td>Hysingla†</td>
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<td></td>
<td>Incruse Ellipta</td>
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<tr>
<td></td>
<td>Kerydin</td>
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Clinical PA Criteria Apply

Granfather Existing Users

3. Age Edit


- **Ceritinib (Zykadia™):**
  Prior authorization is required for ceritinib (Zykadia™). Payment will be considered under the following conditions:
  1. Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test (attach copy of results); and
  2. Patient is 18 years of age or older; and
  3. Prescribed by an oncologist; and
  4. Patient has documentation of treatment with crizotinib and the disease has progressed while on treatment or is intolerant to treatment.
  5. Liver function tests (ALT, AST, and total bilirubin) will be monitored at least monthly while on ceritinib.
If criteria for coverage are met, initial requests will be given for three months. Requests for continuation of therapy will be considered with documentation patient has not experienced disease progression or unacceptable toxicity.

- **Deferasirox (Exjade®)**
  Prior authorization is required for deferasirox. Payment will be considered under the following conditions:
  1. Patient does not have a serum creatinine greater than two times the age-appropriate upper limit of normal or creatinine clearance <40mL/min; and
  2. Patient does not have a poor performance status; and
  3. Patient does not have a high-risk myelodysplastic syndrome; and
  4. Patient does not have advanced malignancies; and
  5. Patient does not have a platelet count <50 x 10⁹/L.

**Transfusional Iron Overload**

**Initiation of Therapy**
  1. Patient is two years of age or older; and
  2. Patient has documentation of iron overload related to anemia (attach documentation); and
  3. Patient has documentation of a recent history of frequent blood transfusions that has resulted in chronic iron overload; and
  4. Serum ferritin is consistently >1000 mcg/L (attach lab results dated within the past month); and
  5. Starting dose does not exceed 20mg/kg/day. Calculate dose to the nearest whole tablet.
  6. Initial requests will be considered for up to three months.

**Continuation of Therapy**
  1. Serum ferritin has been measured within 30 days of continuation of therapy request (attach lab results); and
  2. Ferritin levels are >500mcg/L; and
  3. Dose does not exceed 40mg/kg/day.

**Non-Transfusional Iron Overload**

**Initiation of Therapy**
  1. Patient is 10 years of age or older; and
  2. Patient has documentation of iron overload related to anemia (attach documentation); and
  3. Serum ferritin and liver iron concentration (LIC) has been measured within 30 days of initiation (attach lab results); and
  4. Serum ferritin levels are >300mcg/L.
  5. Liver iron concentration (LIC) are >3mg Fe/g dw; and
6. Dose does not exceed 10mg/kg/day (if LIC is <15mg Fe/g dw), or 20mg/kg/day (if LIC is >15mg Fe/g dw).
7. Initial authorization will be considered for up to six months.

Continuation of Therapy
1. Serum ferritin and LIC have been measured within 30 days of continuation of therapy request; and
2. Serum ferritin levels are >300mcg/L; and
3. Liver iron concentration (LIC) is >3mg Fe/g dw; and
4. Dose does not exceed 10mg/kg/day (if LIC is 3 to 7mg Fe/g dw) or 20mg/kg/day (if LIC is >7mg Fe/g dw).

- Oral Immunotherapy (Oralair®) in addition to currently posted criteria:
  - Patient is 10 through 65 years of age (Oralair®); and
  - Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to sweet vernal, orchard/cocksfoot, perennial rye, timothy, and Kentucky blue/June grass.
  - If criteria for coverage are met, authorization will be considered at least four months prior to the expected onset of each grass pollen season and continued throughout the grass pollen season.

- Vorapaxar (Zontivity™)
Prior authorization is required for vorapaxar (Zontivity™). Payment will be considered under the following conditions:
1. Patient has a history of myocardial infarction (MI) or peripheral artery disease (PAD); and
2. Patient does not have a history of stroke, transient ischemic attack (TIA), intracranial bleeding, or active peptic ulcer; and
3. Patient has documentation of an adequate trial and therapy failure with aspirin plus clopidogrel; and
4. Patient will use vorapaxar concurrently with aspirin and/or clopidogrel.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.


- Apixaban (Eliquis):
  Atrial Fibrillation
  - Requests will be considered for the following dosing:
    - 5mg twice daily; or
    - 2.5mg twice daily in patients with any two (2) of the following:
      - Age ≥80 years
      - Body weight ≤60 kg
Serum creatinine ≥1.5 mg/dL.

Treatment and Prevention of DVT or PE

- Patient has documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial).
- Requests will be considered for the following dosing:
  - Initial Treatment of DVT or PE: 10mg twice daily for 7 days, followed by 5mg twice daily up to 12 months of treatment.
  - Prevention of DVT or PE following initial therapy with standard anticoagulation therapy for 6 to 12 months of treatment for DVT or PE: 2.5mg twice daily.

Prophylaxis of DVT following hip or knee replacement surgery

- Requests will be considered for the following dosing:
  - Hip replacement: 2.5mg twice daily for up to 35 days following hip replacement; or
  - Knee replacement: 2.5mg twice daily for up to 12 days after knee replacement.

Apremilast (Otezla):

Prior authorization is required for apremilast (Otezla®). Payment will be considered under the following conditions:

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of active psoriatic arthritis (≥ 3 swollen joints and ≥ 3 tender joints); or
3. Patient has a diagnosis of moderate to severe plaque psoriasis; and
4. Prescribed by a rheumatologist or a dermatologist; and
5. Patient does not have severe renal impairment (CrCl < 30mL/min).

Plaque Psoriasis

- Patient has documentation of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine; and
- Patient has documentation of trials and therapy failures with two preferred biological agents.

Testosterone Products:

Prior authorization is required for testosterone products. Payment will be considered with documentation of a specific testicular or hypothalamic/pituitary disease (primary hypogonadism or hypogonadotropic hypogonadism) that results in classic hypogonadism. Requests for FDA approved indications other than hypogonadism will not be subject to prior authorization criteria with adequate documentation of diagnosis. Payment for non-preferred testosterone products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred agents. Requests for erectile dysfunction, infertility, and age-related hypogonadism will not be considered. Payment will be considered under the following conditions:
Patient has primary hypogonadism or hypogonadotropic hypogonadism (further defined below):

- **Primary hypogonadism** (congenital or acquired) caused by testicular failure due to one of the following:
  - Cryptorchidism
  - Bilateral torsion
  - Orchitis
  - Vanishing testes syndrome,
  - Orchietomy
  - Klinefelter’s syndrome,
  - Chemotherapy
  - Toxic damage from alcohol or heavy metals
- **Hypogonadotropic hypogonadism**
  - Idiopathic gonadotropin or luteinizing hormone-releasing (LHRH) deficiency
  - Pituitary-hypothalamic injury from tumors, trauma, or radiation

- **Thrombopoietin Receptor Agonists:**
  Requests will not be considered under the following conditions:
  Patients taking direct acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.

Payment for eltrombopag (Promacta®) for the treatment of severe aplastic anemia will only be considered under the following conditions:

1. Patient has documentation of an insufficient response or intolerance to at least one prior immunosuppressive therapy; and
2. Patient has a platelet count less than or equal 30 X 10^9/L.
3. If criteria for coverage are met, initial authorization will be given for 16 weeks. Documentation of hematologic response after 16 weeks of therapy will be required for further consideration.

4. **Point of Sale Billing Issues:**
   a. **ProDUR Quantity Limits:** The following quantity limit edits will be implemented effective June 1, 2015. A comprehensive list of all quantity limit edits appears on our website, www.iowamedicaidpdl.com under the heading, “Quantity Limits”.

<table>
<thead>
<tr>
<th>Drug Product</th>
<th>Quantity</th>
<th>Days Supply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avonex</td>
<td>1 kit</td>
<td>28</td>
</tr>
<tr>
<td>Belsomra 5mg</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Belsomra 10mg</td>
<td>30</td>
<td>30</td>
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<tr>
<td>Belsomra 15mg</td>
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<td>30</td>
</tr>
<tr>
<td>Belsomra 20mg</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Combivent Respimat</td>
<td>8 grams</td>
<td>30</td>
</tr>
<tr>
<td>Entocort 3mg Capsule</td>
<td>90</td>
<td>30</td>
</tr>
<tr>
<td>Victoza</td>
<td>9mL</td>
<td>30</td>
</tr>
<tr>
<td>Vyvanse 10mg</td>
<td>30</td>
<td>30</td>
</tr>
</tbody>
</table>
b. **Fifteen (15) Day Initial Prescription Supply Limit List: Effective June 1, 2015**

The initial fifteen (15) day prescription limit list will be updated. Please refer to the updated list located at [www.iowamedicaidpdl.com](http://www.iowamedicaidpdl.com) under the Preferred Drug Lists link.

d. **Dispensing Fee:** The IME received approval from the Centers for Medicare and Medicaid Services (CMS) to increase the dispensing fee for outpatient pharmacy claims from $10.12 to $11.73. The dispensing fee increase approval is retroactive back to August 1, 2014. System changes for the increased dispensing fee were completed effective September 24, 2014, for claims dated September 24, 2014, and after. The dispensing fee adjustment for claims dated August 1, 2014, through September 23, 2014, was completed on March 20, 2015. Please refer any questions regarding payments to the IME Provider Services Unit at 800-338-7909 or 256-4609 local.

5. **Preferred Brand Name Drugs on the PDL-Pharmacy Clarification**

When a status change occurs for a previously preferred brand name drug to non-preferred status, up to a *minimum* of 30 days transition period is given to pharmacies to help utilize existing brand name product in stock in an effort to decrease a pharmacy's remaining brand name drug inventory (see PDL comment section regarding transition periods exceeding 30 days). If additional stock remains beyond this time period, pharmacies may call the POS Helpdesk at 877-463-7671 or 515-256-4608 (local) to request an override for the non-preferred brand name drug with a recent status change.

6. **DUR Update:** The latest issue of the Drug Utilization Review (DUR) Digest is located at the Iowa DUR website, [www.iadur.org](http://www.iadur.org) under the “Newsletters” link.

We encourage providers to go to the website at [www.iowamedicaidpdl.com](http://www.iowamedicaidpdl.com) to view all recent changes to the PDL. If you have questions, please contact the Pharmacy Prior Authorization Helpdesk at 877-776-1567 or 515-256-4607 (local in Des Moines) or email info@iowamedicaidpdl.com.